

Remarks

Claims 1, 2, 10, 13, 17, and 18 have been amended. Support for the claim amendments may be found throughout the specification, including, but not limited to the following: Claim 1 on Page 22, lines 4-8 and in combination with figures 6 and 12; Claim 2 on Page 21, lines 26-29 in combination with Fig. 13; Claim 10 on Page 16, lines 11-15; Claim 17 on Page 22, lines 4-8 and lines 27-30; and Claim 18 on Page 22, lines 11-14. Applicant respectfully requests the Examiner to enter the claim amendments. And the Applicant respectfully requests an interview with the Examiner at the Examiner's convenience.

Arguments

- I. Claims 1-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

The Examiner stated that the term "continuous circumferential undulation" in claim 1 is used by the claim to mean "a longitudinal undulation", while the accepted meaning is "an undulating structure about the circumference", and the term is indefinite because the specification does not clearly redefine the term. Office Action dated 10/02/08, Page 2. The Applicant has amended Claim 1 to state "circumferential corrugations forming an undulating pattern of peaks and valleys in each of the luminal wall and abluminal wall surfaces of the body member and along at least a portion of the longitudinal axis of the body member". Support for the amended Claim 1 can be found on Claim 1 on Page 22, lines 27-30. Claim 1 is now definite and distinctly claims the subject matter. As such, the Applicant respectfully requests the Examiner to withdraw the rejection of Claims 1-17 rejected under 35 U.S.C. 112, second paragraph.

- II. Claims 1-4 and 13-15, & 17-20 rejected under 35 U.S.C. §103(a) as being unpatentable over Palmaz et al (WO 01/74274) in view of De Goicoechea et al. (U.S. Patent No. 5,383,927)

The Examiner stated that the graft of Palmaz with continuous circumferential undulations as taught by De Goicoechea for the purposes of providing a stronger graft wall renders Claims 1-4, 13-15, and 17-20 obvious to one of ordinary skill in the art. The Applicant respectfully disagrees with the Examiner for the following reasons: First, Palmaz does not teach or disclose a graft with an undulating pattern, any undulating pattern in Palmaz is applied only to stents. *See* Applicant's Supplemental Response filed 02/14/08 to Final Office Action dated 08/22/07, Pages

7-8. Second, any undulations taught by Palmaz are the purposes of stent fabrication, as stated by the Examiner, where the undulations are formed in the walls of the body member. Such undulations in the walls of the body member of a stent are illustrated in Fig. 4 of the cited reference Kula (U.S. 6,325,825) cited by the Examiner.

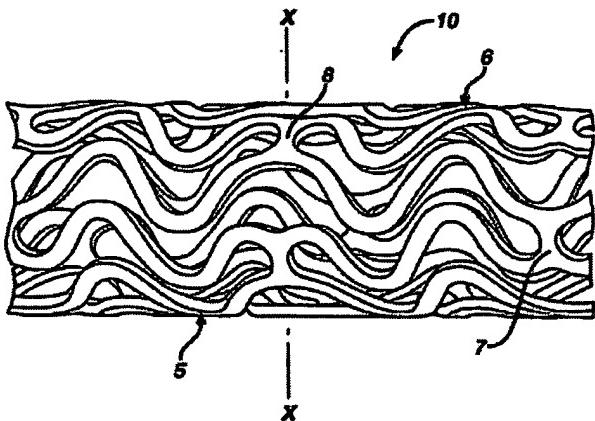


Fig. 4 of Kula shows stent members that undulate coplanar with the tubular wall of the stent and allow for the radial expansion of the stent from an unexpanded form to an expanded form, i.e. circumferential expansion. Kula, Col. 1, lines 1-25, Col. 4, lines 22-31. Contrarily, the graft of De Goicoechea includes a prosthesis with crimps 22 that strengthen the walls of the prosthesis along the radial axis of the prosthesis due to prosthesis being made from polymeric material woven, knitted, or cast into the desired shape for the prosthesis. De Goicoechea, Col. 3, lines 12-24, Col. 7, lines 31-34, Fig. 1A. As such, the crimped plastic prosthesis of De Goicoechea would not radially expand and one of ordinary skill in the art would not use the teachings of De Goicoechea's prosthesis, because inherently stents need to radially expand. Any crimping along the longitudinal axis of the stent would prevent radial expansion. Convincingly, one of ordinary skill in the art of stents would make the stent stronger by varying the spacing and cycling of undulations coplanar with the tubular wall of the stent (Kula, Col. 5, lines 1-67) and not include continuous circumferential undulations to make the stent stronger. Therefore, there is no motivation or suggestion to combine Palmaz with De Goicoechea, as one of ordinary skill in the art could not make a stronger graft wall in Palmaz with the teachings of De Goicoechea.

Moreover, the modification would change the principle of operation of the graft in De Goicoechea or the stent in Palmaz. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP

§2143.02. As stated previously, the crimps in De Goicoechea strengthen the walls of the prosthesis along the radial axis of the prosthesis due to prosthesis being made from polymeric material woven, knitted, or cast into the desired crimped shape for the prosthesis. De Goicoechea, col. 7, lines 31-33. For claim 1, the circumferential corrugations forming an undulating pattern of peaks and valleys in each of the luminal wall and abluminal wall surfaces of the body member and along at least a portion of the longitudinal axis of the body member to impart longitudinal flexibility to the implantable medical graft. The Palmaz stent with structural members that undulate coplanar with the tube combined with the crimps of De Goicoechea would render the medical device inoperable, either as a stent with circumferential crimps to prevent radial expansion, or a graft with structural members that undulate coplanar with the graft tube to prevent the graft for implantation. Accordingly, the Applicants submit that the Claim 1 is nonobvious in light of Palmaz in view of De Goicoechea.

Furthermore, Palmaz in light of De Goicoechea is not enabling for body member having “a plurality of circumferential corrugations forming an undulating pattern of peaks and valleys each of the luminal wall and abluminal wall surfaces of the body member and along at least a portion of the longitudinal axis of the body member”, wherein the body member is formed of “metallic and pseudometallic materials”. De Goicoechea only discloses that the base material may be woven, knitted, or cast into the desired shape for the prosthesis. De Goicoechea, Col. 3, lines 16-23. Palmaz only teaches vacuum deposition to form a cylindrical film and the structural members that may undulate are formed by masking regions of the material blank and then etching the unmasked regions to interstitial webs. Palmaz, Page 18, lines 10-14. Such teachings do not enable one skilled the art to form a body member of metallic and pseudometallic materials having a plurality of circumferential corrugations forming an undulating pattern of peaks and valleys each of the luminal wall and abluminal wall surfaces. As such, the Applicant respectfully request the Examiner to withdraw the rejection of Claims 1-4 and 13-15, under 35 U.S.C. §103(a) as being unpatentable over Palmaz in view of De Goicoechea.

Regarding Claim 17, Applicant has amended Claim 17 to state “circumferential corrugations forming an undulating pattern of peaks and valleys form annular ridges in the body member to permit the implantable medical graft to bend in excess of 180 degrees about the longitudinal axis of the implantable medical graft”. Palmaz in view of De Goicoechea when combined do not teach each and every limitation of Claim 17. As such, the Applicant

respectfully requests the Examiner to withdraw the rejection of Claim 17 as being unpatentable over Palmaz in light of De Goicoechea.

Regarding Claims 18-20, Applicant has amended Claim 18 to state "the proximal and distal ends of the tubular body member include longitudinal regions with annular ridges and other longitudinal regions including no annular ridges to form a staggered array of annular ridged and non-annular ridged regions at the proximal and distal ends of the body member". Palmaz in view of De Goicoechea when combined do not teach each and every limitation of Claim 18. As such, the Applicant respectfully requests the Examiner to withdraw the rejection of Claim 18 and dependent claims 19-20 as being unpatentable over Palmaz in light of De Goicoechea.

III. Claims 5, 12 and 16 rejected under 35 U.S.C. §103(a) as being unpatentable over Palmaz et al. in view of De Goicoechea et al. (U.S. 5,383,927), further in view of Van Schie et al. (U.S. 6,974,471).

As discussed above, the Examiner has failed to establish a *prima facie* case of obviousness with respect to claims 1-4, 13-15 and 17-20. Since independent claims 1 and 13 are nonobvious in view of the prior art, all claims depending therefrom are also nonobvious. Claims 5 and 12, which depend from independent claim 1, and claim 16, which depends from independent claim 13, are, therefore, also nonobvious.

Applicant further note that the suture material referred to in Van Schie et al. is provided in order to create the curved shape of the Van Schie et al. device. The thread-like material is run circumferentially around the Van Schie et al. device in order to impose curvature within the structure. The claimed invention, in contrast, recites suture openings passing through the wall thickness of the graft of the at least one of the non-undulated regions of the body member.

IV. Claims 6-10 rejected under 35 U.S.C. §103(a) as being unpatentable over Palmaz et al. in view of De Goicoechea et al. and Van Schie et al. as applied above, and in further view of Kula et al (U.S. 6,325,825)

Since the Examiner has failed to establish a *prima facie* case of obviousness with respect to independent claims 1 and 13, all claims depending from independent claimis 1 and 13 are also nonobvious. Claims 6-10, which depend from independent claim 1, are, therefore, nonobvious. The Applicant respectfully requests the Examiner to withdraw the rejection of Claims 6-10 accordingly.

The Examiner recognizes that the combination of Palmaz et al. with De Goicoechea et al. and Van Schie et al. does not disclose and lacks "the thickness of the undulating regions as less

than that of the non-undulating regions." The Examiner then asserts that "Kula et al. teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz et al/Van Schie." Applicants respectfully disagree. The thicker ends provided in the Kula et al. stent do not correspond to the varying thicknesses of the undulating and non-undulating regions of the claimed graft. As explained in Kula et al.:

"Other modifications at the ends of the stent 10 may include increasing the thickness of the wall of the stent 10 and selective electropolishing. These modifications protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during insertion of the stent 10."

(Kula et al., col. 4, lines 60-63, underlining added for emphasis.)

Kula provides additional thickness and polishing at the ends of the stent in order to protect vessels from damage caused by the stent ends. This smoothing out of the rough ends of the Kula et al. stent does not correspond to having "the wall thickness of the undulating regions [is] less than the wall thickness of the non-undulating regions" as recited in claim 6. Even with the combination of references, the Examiner has not provided each element of the claims as required for a proper 35 U.S.C. 103(a) rejection.

With respect to claim 7, the Examiner acknowledges that none of the combined references teach or suggest the specific thicknesses recited in claim 7. The Examiner, nonetheless, rejects claim 7 as being obvious. Applicants note that the Examiner has not provided any prior art reference that renders the claimed thicknesses obvious.

With respect to claims 9 and 10, the Examiner acknowledges that none of the references teach or even suggest the "generally cruciform-shaped slot pattern" recited in claim 9 or the "generally Y-shaped slot pattern" recited in claim 10. Nonetheless, the Examiner rejects claims 9 and 10 as being obvious. Applicants once again note that the Examiner has failed to provide any prior art reference that would render claims 9 or 10 obvious. Because the Examiner has made these conclusory statements without citing any prior art reference in support of his conclusion, Applicants interpret the Examiner's statement to be an official notice. Applicants traverse the Examiner's official notice and request that the Examiner provide evidentiary support for this official notice.

The rejection of claims 6-10 under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al. in view of De Goicoechea et al. and Van Schie et al., and further in view of Kula et al. is improper, and Applicants respectfully request withdrawal of this rejection.

V. Claim 11 rejected under 35 U.S.C. §103(a) as being unpatentable over Palmaz et al and De Goicoechea et al., as applied above and further in view of Banas et al. (U.S. 5,749,880)

Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al. in view of De Goicoechea et al., and further in view of Banas et al. (U.S. Patent No. 5,749,880). As discussed above, the Examiner has failed to establish a *prima facie* case of obviousness with respect to independent claim 1. Since independent claim 1 is nonobvious in view of the prior art, claim 11, which depends from independent claim 1, is also nonobvious.

CONCLUSION

Applicants respectfully request that the Examiner withdraw the rejections of claims 1-20 based on the remarks presented herein. Applicants also formally request an interview with the Examiner to discuss such remarks and claim amendments presented herein. The Examiner is also welcome to telephone the undersigned attorney of record if the Examiner believes that there are any outstanding matters capable of resolution by a telephone interview.

This Amendment is being submitted with a check in payment of the required three (3) month extension of time. No additional fees are believed due, however, the Director is hereby authorized to charge any under payment of fees, or credit any overpayment to Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Respectfully submitted,



J. Peter Paredes
Reg. No.57,463

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ROSENBAUM & ASSOCIATES, P.C.
650 Dundee Road
Suite #380
Northbrook, Illinois 60062
Tel. (847) 770-6000
Fax. (847) 770-6006
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